DISCUS DENTAL
INCORPORATED

JUN 18 2004

II. Summary of Safety and Effectiveness

ProActive Care™ Prophylaxis Paste with Fluoride

1. **Date of Summary:**

2. **Date of Summary Preparation:** November 20, 2003

3. **Applicant:** Discus Dental, Inc.

4. **Contact Person:**

Vivian Lai, MS
Associate, Regulatory Affairs
Discus Dental, Inc.
8550 Higuera Street
Culver City, CA 90232
310.845.8347
310.845.1537

5. **Name of Medical Device:**

Proprietary Name: ProActive Care™ Prophylaxis Paste with Fluoride

Common/Usual Name: Prophylaxis Paste

Classification Name: Oral cavity abrasive polishing agent

6. **Description of Medical Device**

The ProActive Care™ is a premium Prophylaxis Paste with fluoride that gently removes dental plaque and staining. It is a unique blend of polishing and cleaning agents designed for professional application during standard dental practice hygiene procedures.

7. **Intended Use**

The ProActive Care™ Prophylaxis Paste with Fluoride is to be used for cleaning and polishing procedures as part of a professionally administrated prophylaxis treatment.

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8. Substantial Equivalence Determination

The ProActive Care™ Prophylaxis Paste is substantially equivalent to the following products:

a) Nupro® T Prophylaxis Paste with Fluoride and Triclosan (K000169)

b) ProClude® (K002989)

c) 3M™ Clinpro™ Prophy Paste (K990482)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2004

Ms. Vivian Lai
Associate, Regulatory Affairs
Discus Dental, Incorporated
8550 Higuera Street
Culver City, California 90232

Re: K033785
Trade/Device Name: ProActive Care™ Prophylaxis Paste with Fluoride
Regulation Number: 872.6030
Regulation Name: Oral Cavity Abrasive Polishing Agent
Regulatory Class: I
Product Code: EJR
Dated: March 31, 2004
Received: March 5, 2004

Dear Ms. Lai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Indications for Use Statement

510 (k) Number: K033785

Device Name: ProActive Care™ Prophylaxis Paste

Indications for Use:

To be used for cleaning and polishing procedures as part of a professionally administered prophylaxis treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
Per 21 CFR Section 801.109

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033785

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